

U.S.S.N. 10/706,243

Filed: November 12, 2003

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

**Amendment**

Claims 1-15 (canceled).

16. (previously presented) Dry microparticles having a size range of between 0.5 and ten microns comprising a drug to be delivered by inhalation, wherein the microparticles are formed of a material releasing drug at a pH of greater than 6.0, wherein the material is selected from the group consisting of proteins, mixed amino acids, polysaccharides, lipids and surface active agents.

17. (previously presented) The dry microparticle of claim 16 wherein the material is a surface active agent or surfactant.

18. (previously presented) The dry microparticle of claim 16 wherein the material is a lipid.

19. (previously presented) The dry microparticle of claim 16 wherein the proteins are hydrophilic proteins.

20. (previously presented) The dry microparticle of claim 16 wherein the proteins are hydrophobic proteins.

21. (previously presented) The dry microparticle of claim 16 wherein the polysaccharides are selected from the group consisting of aliginate and chitosan.

22. (previously presented) A cartridge for insertion into an inhaler comprising dry microparticles having a size range of between 0.5 and ten microns comprising a drug to be delivered by inhalation, wherein the microparticles are formed of a material releasing drug at a

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pH of greater than 6.0, wherein the material is selected from the group consisting of proteins, mixed amino acids, polysaccharides, lipids and surface active agents.

23. (previously presented) A method for delivery of microparticles to the pulmonary system comprising: administering to a patient in need of treatment an effective amount of microparticles which comprise a diketopiperazine and which have a diameter between 0.5 microns and ten microns, in a pharmaceutically acceptable carrier for administration to the lungs, wherein the carrier is air.

24. (previously presented) The method of claim 23, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and fumaryl.

25. (previously presented) The method of claim 24, wherein X is fumaryl.

26. (previously presented) The method of claim 23, wherein the agent is a therapeutic agent selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (G-CSF), lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,  $\beta$ -galactosidase, and Argatroban.

27. (previously presented) A microparticulate system for controlled drug delivery to the pulmonary system comprising: microparticles incorporating therein a therapeutic, prophylactic or diagnostic agent, wherein the microparticles have a diameter between 0.5 microns and ten microns and are formulated to release the incorporated agent at a pH of 6.0 or greater under

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conditions present in the pulmonary system, in a pharmaceutically acceptable carrier for administration to the lungs, wherein the carrier is air, and wherein the microparticles are made from a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), polyanhydrides, polyesters, polyamides, polycarbonates, polyalkylenes, polyvinyl compounds, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), polysaccharides, copolymers and mixtures thereof.

28. (previously presented) The system of claim 27, wherein the material is a diketopiperazine.

29. (previously presented) The system of claim 28, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and fumaryl.

30. (previously presented) The system of claim 29, wherein X is fumaryl.

31. (previously presented) The system of claim 27, wherein the agent is a therapeutic agent selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (G-CSF), lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,  $\beta$ -galactosidase, and Argatroban.

32. (previously presented) A method for controlled drug delivery to the pulmonary system comprising: administering to a patient in need of treatment an effective amount of

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microparticles incorporating therein a therapeutic, prophylactic or diagnostic agent, wherein the microparticles have a diameter between 0.5 microns and ten microns and are formulated to release the incorporated agent at a pH of 6.0 or greater under conditions present in the pulmonary system, in a pharmaceutically acceptable carrier for administration to the lungs, wherein the carrier is air, and wherein the microparticles are made from a material selected from the group consisting of diketopiperazines, poly(hydroxy acids), polyanhydrides, polyesters, polyamides, polycarbonates, polyalkylenes, polyvinyl compounds, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), polysaccharides, copolymers and mixtures thereof.

33. (previously presented) The method of claim 32, wherein the material is a diketopiperazine.

34. (previously presented) The method of claim 33, wherein the diketopiperazine has the formula 2, 5 -diketo-3,6-di(4-X-aminobutyl)piperazine, wherein X is selected from the group consisting of succinyl, glutaryl, maleyl, and fumaryl.

35. (currently amended) The method of claim 34, wherein X is fumaryl.

36. (previously presented) The method of claim 32, wherein the agent is a therapeutic agent selected from the group consisting of insulin, calcitonin, felbamate, heparin, parathyroid hormone and fragments thereof, growth hormone, erythropoietin, zidovudine (AZT), didanosine (DDI), granulocyte colony stimulating factor (G-CSF), lamotrigine, chorionic gonadotropin releasing factor, luteinizing releasing hormone,  $\beta$  -galactosidase, and Argatroban.